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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,166	07/09/2003	Rourke M. Yeakley	YEAR102	2728

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EXAMINER	
KEASEL, ERIC S	

ART UNIT	PAPER NUMBER
3754	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,166	YEAKLEY, ROURKE M.	
	Examiner	Art Unit	
	Eric Keasel	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/8/03&11/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on January 9, 2006 is acknowledged.

2. Claim 17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 9, 2006.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the squeezable propellant chamber and the expelling material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because of the use of legal phraseology "comprised". Correction is required. See MPEP § 608.01(b).

Claim Objections

6. Claim 9 is objected to because in line 7, it appears that "brake said membrane" should be --break said membrane-- and in line 8, it appears that "pressue" should be --pressure--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeberg et al. (US Patent Number 3,327,710).

Freeberg et al. disclose a self-contained dispensing system for dispensing measured amounts of medication stored in a powdered form (22) comprising: an ampule (see generally at Fig. 1) having a first chamber (21) configured to hold a premeasured amount of a selected medication stored in a powdered form (22) therein, and a second chamber (28) configured to hold a premeasured amount of a reconstituting liquid (29) therein, said first chamber separated from said second chamber by a breakable membrane (36), said ampule configured to allow an individual to break said membrane to suspend said powder within said reconstituting liquid and to allow said suspension to be dispensed from said ampule through an opening (in 19) in said ampule when pressure is applied to said ampule; wherein said ampule further comprises a squeezable propellant chamber (i.e. plunger 18 is squeezed into cylinder 13), said propellant chamber configured to contain a designated quantity of an expelling material (including air), said propellant chamber configured to compress when a designated quantity of pressure is applied to said propellant chamber and to force said expelling material and said medication out of said ampule; further comprising a puncturing device (40) configured to create said opening within said ampule; wherein said puncturing device is calibrated to create an opening of a desired size within said ampule (at least as calibrated as applicant's puncturing device is calibrated); further comprising a container configured to hold said ampule and said puncturing device, in a sealed environment (see generally at Fig. 1, the entire device is a sealed container); and wherein said puncturing device is a portion of said container.

9. Claims 1-7 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mukasa et al. (US Patent Number 6,386,872).

Mukasa et al. disclose a self-contained dispensing system for dispensing measured amounts of medication stored in a powdered form (A) comprising: an ampule (see generally at Fig. 1) having a first chamber (1a) configured to hold a premeasured amount of a selected medication stored in a powdered form (A) therein, and a second chamber (2a) configured to hold a premeasured amount of a reconstituting liquid (B) therein, said first chamber separated from said second chamber by a breakable membrane (2c), said ampule configured to allow an individual to break said membrane to suspend said powder within said reconstituting liquid and to allow said suspension to be dispensed from said ampule through an opening (1c, 4a) in said ampule when pressure is applied to said ampule; wherein said ampule further comprises a squeezable propellant chamber (i.e. plunger 3 is squeezed into cylinder 2), said propellant chamber configured to contain a designated quantity of an expelling material (including air), said propellant chamber configured to compress when a designated quantity of pressure is applied to said propellant chamber and to force said expelling material and said medication out of said ampule; further comprising a puncturing device (3a) configured to create said opening within said ampule; wherein said puncturing device is calibrated to create an opening of a desired size within said ampule (at least as calibrated as applicant's puncturing device is calibrated); further comprising a container configured to hold said ampule and said puncturing device, in a sealed environment (see generally at Fig. 1, the entire device is a sealed container); and wherein said puncturing device is a portion of said container.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 6, 8, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeberg et al. in view of Schmid (US Patent Number 5,819,921).

Freeberg et al. disclose a self-contained dispensing system for dispensing measured amounts of medication stored in a powdered form (22) comprising: an ampule (see generally at Fig. 1) having a first chamber (21) configured to hold a premeasured amount of a selected medication stored in a powdered form (22) therein, and a second chamber (28) configured to hold a premeasured amount of a reconstituting liquid (29) therein, said first chamber separated from said second chamber by a breakable membrane (36), said ampule configured to allow an individual to break said membrane to suspend said powder within said reconstituting liquid and to allow said suspension to be dispensed from said ampule through an opening (in 19) in said ampule when pressure is applied to said ampule; wherein said ampule further comprises a squeezable propellant chamber (i.e. plunger 18 is squeezed into cylinder 13), said propellant chamber configured to contain a designated quantity of an expelling material (including air), said propellant chamber configured to compress when a designated quantity of pressure is applied to said propellant chamber and to force said expelling material and said medication out of said ampule; further comprising a puncturing device (40) configured to create said opening within

said ampule; and wherein said puncturing device is calibrated to create an opening of a desired size within said ampule (at least as calibrated as applicant's puncturing device is calibrated).

In an alternate reading of the Freeberg et al. reference, they fail to disclose a separate container (generally rectangular), with a bottom portion of the container configured to contain the puncturing device. Schmid discloses a similar ampule that rests in the bottom of a generally rectangular container (see Fig. 4). It would have been obvious to one having ordinary skill in the art to have placed the ampule (including the puncturing device) of Freeberg et al. in the container of Schmid in order to create a package that can be sterilized as a unit as taught by Schmid.

12. Claims 6, 8, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mukasa et al. in view of Discko, Jr. (US Patent Number 5,199,567).

Mukasa et al. disclose a self-contained dispensing system for dispensing measured amounts of medication stored in a powdered form (A) comprising: an ampule (see generally at Fig. 1) having a first chamber (1a) configured to hold a premeasured amount of a selected medication stored in a powdered form (A) therein, and a second chamber (2a) configured to hold a premeasured amount of a reconstituting liquid (B) therein, said first chamber separated from said second chamber by a breakable membrane (2c), said ampule configured to allow an individual to break said membrane to suspend said powder within said reconstituting liquid and to allow said suspension to be dispensed from said ampule through an opening (1c, 4a) in said ampule when pressure is applied to said ampule; wherein said ampule further comprises a squeezable propellant chamber (i.e. plunger 3 is squeezed into cylinder 2), said propellant chamber configured to contain a designated quantity of an expelling material (including air), said

propellant chamber configured to compress when a designated quantity of pressure is applied to said propellant chamber and to force said expelling material and said medication out of said ampule; further comprising a puncturing device (3a) configured to create said opening within said ampule; and wherein said puncturing device is calibrated to create an opening of a desired size within said ampule (at least as calibrated as applicant's puncturing device is calibrated.

In an alternate reading of the Mukasa et al. reference, they fail to disclose a separate container (generally rectangular), with a bottom portion of the container configured to contain the puncturing device. Discko, Jr. discloses a similar ampule that rests in the bottom of a generally rectangular container (see Fig. 1). It would have been obvious to one having ordinary skill in the art to have placed the ampule (including the puncturing device) of Mukasa et al. in the container of Discko, Jr. so that the rectangular trays can be incorporated into a rack system as taught by Discko, Jr.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cohen and Cheikh disclose similar disclose similar devices.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Keasel whose telephone number is (571) 272-4929. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Mar can be reached on (571) 272-4906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Keasel
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